Supreme Court, U. S.
FILED
JUN 19 1979
MICHAEL RODAK, JR. CLERK

No. 78-1725

In the Supreme Court of the United States

OCTOBER TERM, 1978

ARTICLES OF FOOD, ETC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

WADE H. MCCREE, JR.
Solicitor General
Department of Justice
Washington, D.C. 20530

In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1725

ARTICLES OF FOOD, ETC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

Petitioners contend that the courts below erred in holding that sodium nitrate and sodium nitrite, when used as components in a processed buffalo meat product ("Buffalo Jerky"), are unsafe food additives within the meaning of 21 U.S.C. 321(s) and 348(a).

1. The United States filed a complaint seeking condemnation of certain articles of food (branded as "Buffalo Jerky") pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* The complaint alleged that "Buffalo Jerky" is adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) because it contains sodium nitrate and sodium nitrite, which are unsafe food additives as defined under 21 U.S.C. 321(s) and 348(a).

The district court granted the government's motion for summary judgment (Pet. App. 1-9). It held that sodium nitrate and sodium nitrite are food additives within the

meaning of 21 U.S.C. 321(s) on the basis of a stipulation that they are components of "Buffalo Jerky" and uncontroverted affidavits demonstrating that they are not generally recognized among experts as safe when used to process buffalo meat (Pet. App. 4).[1] The district court also concluded that the Federal Meat Inspection Act, 21 U.S.C. 601 *et seq.*, does not authorize the use of such food additives since that statute has no application to buffalo meat (*id.* at 5-7). In light of the fact that "Buffalo Jerky" contains food additives that are not approved under FDA exemptions or regulations, the district court held that the product was adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) (*id.* at 7-8). The court of appeals affirmed (*id.* at 10-11).

2. Petitioner contends (Pet. 7-11) that the district court erred in concluding that sodium nitrate and sodium nitrite are "food additives." Petitioner also contends that the question whether a particular substance is an "additive" cannot depend on the nature of the food to which it is added (Pet. 10).

However, 21 U.S.C. 321(s) defines the term "food additive" as follows:

> [A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * * if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) *to be safe under the conditions of its intended use* * * * [emphasis supplied].

Thus, a substance that is a food component is an "additive" subject to the provisions of the Act unless it is generally recognized to be safe under the conditions of its intended use. For this reason, a substance may be deemed to be an "additive" in certain uses but not in others, depending on the amount of the substance that is introduced and the nature of the food that is treated.[2] On the basis of uncontroverted affidavits, the district court properly found that sodium nitrate and sodium nitrite are not generally recognized as safe when used to cure buffalo meat. That factual finding was a sufficient predicate for the determination that sodium nitrite and sodium nitrate constitute "additives" within the meaning of the Act. The court of appeals affirmed this factual determination, and there is no need for further review in this Court. *Berenyi* v. *Immigration Director*, 385 U.S. 630, 635 (1967).[3]

---

[1]The parties stipulated that buffalo (bison) meat is an ingredient in "Buffalo Jerky" (Pet. 4). The affidavits filed by the government established that sodium nitrate and sodium nitrite pose potential health hazards when used to cure various kinds of meat because they can cause the formation of chemical substances (nitrosamines) which are known to cause cancer in experimental animals (Pet. 15).

[2]This principle is illustrated by the FDA's regulations, which recognize that sodium nitrate and sodium nitrite are safe only when used in certain quantities in curing certain meat products. See 21 C.F.R. 172.170; 21 C.F.R. 172.175.

[3]Food "additives" are conclusively deemed to be "unsafe" under 21 U.S.C. 348 unless an exemption has been granted by the Secretary of Health, Education, and Welfare or a regulation has been promulgated permitting their use. No such exemption or regulation exists in this case (Pet. App. 7-8).

3. Contrary to petitioner's assertion (Pet. 11-14), buffalo meat treated with sodium nitrate and sodium nitrite is not subject to the provisions of the Federal Meat Inspection Act.[4] The Federal Meat Inspection Act is concerned only with "meat food products," which it defines in the following limited terms (21 U.S.C. 601(j); emphasis supplied):

> [A]ny product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any *cattle, sheep, swine, or goats* * * *. This term as applied to food products of *equines* shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

As the district court noted, buffalo or bison meat is not included within this definition (Pet. App. 6). The definition includes only ranch and farm livestock, customarily used in the commercial production of meat products.[5] In light of the fact that the Department of Agriculture has never interpreted the Meat Inspection Act

[4]If the sale of buffalo (bison) meat cured with sodium nitrate and sodium nitrite was "in accordance with a sanction or approval" granted by the Department of Agriculture under the Meat Inspection Act, 21 U.S.C. 601 *et seq.*, sodium nitrite and sodium nitrate would be exempt from the definition of food "additive" under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. 321(s)(4).

[5]Congress' failure to include buffalo or bison meat in the Federal Meat Inspection Act of 1907 is not surprising. By 1907 the American buffalo was nearly extinct. A census of the buffalo herd in 1903 showed that only 34 wild bison were left in the United States. The rest of the surviving buffalo were kept in zoos. See 4 *Encyclopaedia Britannica* ("Bison") (1911).

to include buffalo meat products, the district court was clearly correct in declining to rewrite the statute to include a variety of meat not covered by its literal terms.[6]

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

WADE H. MCCREE, JR.
Solicitor General

JUNE 1979

[6]Moreover, even assuming that buffalo meat should be viewed as a meat product subject to the Federal Meat Inspection Act, petitioner wholly failed to show that "Buffalo Jerky," processed with sodium nitrate and sodium nitrite, was "in accordance with a sanction or approval" of the Department of Agriculture. The Department's regulations do allow use of sodium nitrate and sodium nitrite as curing agents, but only in limited quantities. See 9 C.F.R. 318.7(c). Petitioners made no showing that "Buffalo Jerky" contains sodium nitrate and sodium nitrite in legally permissible amounts, and thus failed to show the availability of an "approval" under the Meat Inspection Act that would justify an exemption from the coverage of the Food, Drug, and Cosmetic Act. That burden of demonstration rested on petitioners. See *United States* v. *1,048,000 Capsules, More or Less etc.*, 347 F. Supp. 768, 770 (S.D. Tex. 1972), aff'd, 494 F. 2d 1158 (5th Cir. 1974); *United States* v. *An Article of Drug "Bentex Ulcerine"*, 469 F. 2d 875, 878 (5th Cir. 1972), cert. denied, 412 U.S. 938 (1973).